Sheet



5

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

1

COMPLETE IF KNOWN				
Application Number	09/296,662			
Filing Date	April 22, 1999			
First Named Inventor	Rosen, et al.	PEV		
Group Art Unit	1644	0 200 2		
Examiner Name	NOCAN	FEB 1 R		
Attorney Docket Number	20221Y	PATE OF THE PATE O		

		OTHER NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
PN		Casciano, et al., "Selective Cleavage of Nuclear Autoantigens During CD95 (Fas/APO-1)-mediated T Cell Apopsotis", J. Exp. Med., Vol. 184, August 1996, pp. 765-770.
	2	Casciano, et al., "Antinuclear autoantibodies: probes for defining proteolytic events associated with apoptosis", Molecular Biology Reports, Vol. 23, pp. 211-216, 1996.
	3	Rosen, et al., "Macromolecular Substrates for the ICE-Like Proteases During Apoptosis", Journal of Cellular Biochemistry, Vol. 64, pp. 50-54, 1997.
	4	Bach, et al., "New clues to systemic lupus", Lancet, Vol 350, pp. 11, 1997.
	5	Beidler, et al., "The baculovirus p35 protein inhibits Fas- and tumor necrosis factor-induced apoptosis", J. Biol. Chem., Vol. 270, pp. 16526-16528, 1995.
	6	Bockenstedt, et al., "Self-peptides in the initiation of lupus autoimmunity", J. Immunol., Vol. 154, pp. 3516-3524, 1995.
	7	Bump, et al., "Inhibition of ICE family proteases by baculovirus antiapoptotic protein p35", Science, Vol. 269, pp. 1885-1888, 1995.
	8	Burlingame, et al., "Genesis and evolution of antichromatin autoantibodies in muring lupus implicates T-dependent immunization with self-antigen", J. Clin. Invest., Vol. 91, pp. 1687-1696, 1993.
	9	Casciola-Rosen, et al., "Autoantigens targeted in systemic lupus erythematosus are clustered in two populations of surface structures on apoptotic keratinocytes", J. Exp. Med., Vol. 179, pp. 1317-1330, 1994.
	10	Casciola-Rosen, et al., "Specific cleavage of the 70-kDa protein component of the U1 small nuclear ribonucleoprotein is a characteristic biochemical feature of apoptotic cell death", J. Biol. Chem., Vol. 269, pp. 30757-30760, 1994.
	//	Casciola-Rosen, et al., "DNA-dependent protein kinase is one of a subset of autoantigens specifically cleaved early during apoptosis", J. Exp. Med., Vol. 182, pp. 1625-1634, 1995.
	12	Casciola-Rosen, et al., "Apopain/CPP32 cleaves proteins that are essential for cellular repair: A fundamental principal of apoptotic death", J. Exp.Med., Vol 183, pp. 1957-1964, 1996.
	13	Casciola-Rosen, et al., "Ultraviolet light-induced keratinocyte apoptosis: A potential mechanism for the induction of skin lesions and autoantibody production in L.E.", Lupus, Vol. 6, pp. 175-180, 1997.
	14	Chinnaiyan, et al., "The Cell-Death Machine", Curr. Biol., Vol, 6, pp. 555-562, 1996.
<b>V</b>	/5	Chinnaiyan, et al., "Cytotoxic T-cell-derived granzyme B activates the apoptotic protease ICE-LAP3", Curr. Biol., Vol. 6, pp. 897-899, 1996.

Examiner Signature	Patrick J-Nolon	Date Considered	3/21/01	

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet

COMPLETE IF KNOWN

09/296,662

20221Y



## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Filing Date April 22, 1999

First Named Inventor Rosen, et al.

(use as many sheets as necessary)

of

5

2

Group Art Unit

Examiner Name

NOLAN

**Application Number** 

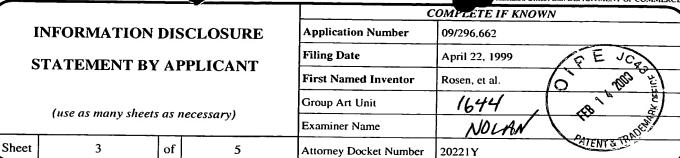
Attorney Docket Number

HB 1 4 2000 C

		OTHER NON PATENT LITERATURE DOCUMENTS
Examiner Cite Initials* No.		Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
AN	16	Darmon, et al., "Cleavage of CPP32 by granzyme B represents a critical role for granzyme B in the induction of target cell DNA fragmentation", J. Biol. Chem., Vol. 271, pp. 21709-21712, 1996.
	17	Darmon, et al., "Activation of the apoptotic protease CPP32 by cytotoxic T-cell-derived granzyme B", Nature, Vol. 377, pp. 446-448, 1995.
	18	Deveraux, et al., "X-linked IAP is a direct inhibitor of cell-death proteases", Nature, Vol. 38, pp. 300-304, 1997.
	19	Diamond, et al., "The role of somatic mutation int he pathogenic anti-DNA response", Ann. Rev. Immunol., Vol. 10, 731-757, 1992.
	20	Duan, et al., "ICE-LAP6, a novel member pf tje ICE/Ced-3 gene family, is activated by the cytotoxic T cell protease granzyme B", J. Biol. Chem., Vol. 271, pp. 16720-16724.
	2/	Fernandes-Alnemri, et al., "In vitro activation of CPP32 and Mch3 by Mch4, a novel human apoptotic cysteine protease containing two FADD-like domains, Proc. Natl. Acad. USA, Vol. 93, pp. 7464-7469, 1996.
,×	22	Froelich, et al., "Granzyme B perforin-mediated apoptosis of jurkat cells results in cleavage of poly(ADP-ribose)polymerase to the 89-kDa apoptotic fragment and less abundant 64-kDa fragment", Biochem. Biophys. Res. Commun., Vol. 227, pp. 658-665. 1996.
	23	Froelich, et al., "New paradigm for lymphocyte granule-mediated cytotoxicity - Target cells bind and internalize granzyme B, but an endosomolytic agent is necessage for cytoxolic delivery and subsequent apoptosis", J. Biol. Chem., Vol. 271, pp. 29073-29079, 1996.
	24	Ghayur, et al., "Proteolytic activation of protein kinase C d by an ICE/CED-3-like protease induces features of apoptosis", J. Exp. Med., Vol. 184, pp. 2399-2404, 1996.
	25	Greidinger, et al., "Sequential activation of three distinct ICE-like activities in Fas-ligated Jurkat cells., "FEBS Lett., Vol. 390, pp. 299-303, 1996.
	26	Gu, et al., "Processing and Activation of CMH-1 by Granzyme B., J. Biol. Chem., Vol. 271, pp. 10816-10820, 1996.
	27	Heusel, et al., "Cytocoxic lymphocytes require gramzyme B for the rapid induction of DNA fragmentation and apoptosis in allogeneic target cells", Cell, Vol. 76, pp. 997-987, 1994.
	રફ	Irmler, et al., "Inhibition of death receptor signals by cellular FLIP, Nature, Vol. 388, pp. 190-195, 1997.
	29	Jacobson, et al., "Programmed cell death in animal development", Cell, Vol. 88, pp. 347-354, 1997.
1	30	Jans, et al., "Nuclear transport of granzyme B (fragmentin 2). Dependence on perforin in vivo and cytosolic factors in vitro", J. Biol. Chem., Vol. 271, pp. 30781-30789, 1996.

Examiner Signature Patrick J-Nolan Date Considered 3/24/0/

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



OTHER NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.		
PN	اح	Krajewska, et al., "Immunohistochemical analysis of in vivo patterns of expression of CPP32 (Caspase-3), a cell death protease", Cancer Res., Vol. 57, pp. 1605-1613, 1997.		
	32	Krajewski, et al., "Immunolocalizationo f the ICE/Ced-3-family protease, CPP32 (Caspase-3), in non-Hodgkin's lymphomas, chronic lymphocytic leukemias, and reactive lymph nodes", Blood, Vol. 89, pp. 3817-3825, 1997.		
	33	Lanzavecchia, et al., "How can cryptic epitopes trigger autoimmunity?", J. Exp. Med., Vol. 181, pp. 1945-1948, 1995.		
	34	Liu, et al., "DFF, a heterodimeric protein that functions downstream of caspase-3 to trigger DNA fragmentation during apoptosis", Cell, Vol. 89, pp. 175-184, 1997.		
	35	Mamula, et al., "The inability to process a self-peptide allows autoreactive T cells to escape tolerance", J. Exp. Med., Vol. 177, pp. 567-571, 1993.		
	36	Martin, et al., "The cytotoxic cell protease gramzyme B initiates apoptosis in a cell-free system by proteolytic processing and activation of the ICE/CED-3 family protease, CPP32, via a novel two-step mechanism", EMBO J., Vol. 15, pp. 2407-2416, 1996.		
	37	Martin, et al., "Protease activation during apoptosis: Death by a thousand cuts?", Cell, Vol. 82, pp. 349-352, 1995.		
	38	McGahon, et al., "Regulation of the Fas apoptotic cell death pathway by Abl. J. Biol. Chem., Vol. 270, pp. 22625-22631, 1995.		
	39	Muzio, et al., "FLICE, a novel FADD-homologous ICE/CED-3-like protease, is recruited to the CD95 (Fas/APO-1) death-inducing signaling complex", Cell, Vol. 85, pp. 817-827, 1996.		
	40	Nicholson, et al., Identification and inhibition of the ICE/CED-3 protease necessary for mammalian apoptosis", Nature, Vol. 376, pp. 37-43, 1995.		
	41	Nicholson, et al., "Caspases: Killer proteases", TIBS, Vol. 22, pp. 299-306, 1997.		
	42	Odake, et al., "Human and murine cytotoxic T lymphocyte serine proteases: Subsite mapping with peptide thioester substrates and inhibition of enzyme activity and cytolysis by isocoumarins", Biochemistry, Vol. 30, pp. 2217-2227, 1991.		
	43	Pinkoski, et al., "Binding of granzyme B in the nucleus of target cells. Recognition of an 80 kDa protein", J. Biol. Chem., Vol. 271, pp. 10225-10229, 1996.		
	44	Podack, et al., "Cytolytic T cell granules. Isolation, structural, biochemical and functional characterization", J. Med. Exp., Vol. 160, pp. 695-710, 1984.		
<b>V</b>	45	Poe, et al., "Human cytotoxic lymphocute gramzyme B: Its purification from granules and the characterization of substrace and inhibitor specificity", J. Biol. Chem., Vol. 266, pp. 98-103, 1991.		

Examiner	// / //	Date	1 1
Signature	Hotarch V-alla	1 ~ ., .	<b>5</b> /
J.B.Iarare	Patries V-No an	Considered	5/2//0/

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



## COMPLETE IF KNOWN INFORMATION DISCLOSURE **Application Number** 09/296,662 Filing Date STATEMENT BY APPLICANT April 22, 1999 First Named Inventor Rosen, et al. Group Art Unit (use as many sheets as necessary) Examiner Name Sheet 4 of 5 Attorney Docket Number 20221Y

Evenine	- I C:-	OTHER NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
PN	46	Quan, et al., "Proteolytic activation of the cell death protease Yama/CPP32 by granzyme B., Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 1972-1976, 1996.
	47	Radic, et al., "Genetic and structural evidence for antigen selection of anti-DNA antibodies", Ann. Rev. Immunol., Vol. 12, pp. 487-520, 1994.
	48	Ramage, et al., "Expression, refolding, and autocatalytic proteolytic processing of the interleukin-1b-converting enzyme precursor", J. Biol. Chem., Vol. 270, pp. 9378-9383, 1995.
	49	Salemi, et al., "HIVgp120 activates autoreactive CD4-specific T cell responses by unveiling of hidden CD4 peptides during processing", J. Exp. Med., Vol. 181, pp. 2253-2257, 1995.
	50	Sarin, et al., "Target cell lysis by CTL granule exocytosis is independent of ICE/Ced-3 family proteases", Immunity, Vol. 6, pp. 209-215, 1997.
	51	Sercarz, et al., "Dominance and crypticity of T cell antigenic determinants, Ann. Rev. Immunol., Vol. 11, pp. 729-766, 1993.
	52	Sercarz, et al., "Mechanisms of autoimmunization: perspective from the mid-90s", Curr. Opin. Immunol., Vol. 6, pp. 875-881, 1994.
	53	Shi, et al., "Granzyme B(GraB) autonomously crosses the cell membrane and perforin initiates apoptosis and GraB nuclear localization", J. Exp. Med., Vol. 185, pp. 855-866, 1997.
	54	Shresta, et al., "Natural killer and lymphokine-activated killer cells require granzyme B for the rapid induction of apoptosis in susceptible target cells", Proc. Natl. Acad. Sci. USA, Vol. 92, pp. 5679-5683, 1995.
	55	Simitsek, et al., "Modulation of antigen processing by bound antibodies can boost or suppress class II major histocompatibility complex presentation of different T cell determinants", J. Exp. Med., Vol. 181, pp. 1957-1963, 1995.
	56	Song, et al., "Interleukin-1b converting enzyme-like protease cleaves DNA-dependent protein kinase in cytotoxic T cell killing", J. Exp. Med., Vol. 184, pp. 619-626, 1996.
5	7	Song, et al., "DNA-dependent protein kinase catalytic subunit: A target for an ICE-like protease in apoptosis, EMBO J., Vol. 15, pp. 3238-3246, 1996.
	58	Srinivasula, et al., "The Ced-3-interleukin 1b converting enzyme-like homolog Mch6 and the lamin-cleaving enzyme Mch2a are substrates for the apoptotic mediator CPP32, J. Biol. Chem., Vol. 271, pp. 27099-27106, 1996.
3	59 E	Grinivasula, et al., "FLAME-1, a novel FADD-like anti-apoptotic molecule that regulates Fas/TNFR-1-induced apoptosis, J. Biol. Chem., Vol. 272, pp. 18542-18545, 1997.
4 6		Calanian, et al., "Granule-mediated killing: Pathways for granzyme B-initiated apoptosis", J. Exp. Med., Vol. 86, pp. 1323-1331, 1997.

Examiner Signature	Patrick J-NOGon	Date Considered	3/2/101
Examiner: Initial if mo			212/10/

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number 09/296,662

Filing Date April 22, 1999

First Named Inventor Rosen, et al.

Group Art Unit 644

Examiner Name 1000 AN 7 1000

20221Y

COMPLETE IF KNOWN

(use as many sheets as necessary)

Sheet 5 of 5

OTHER NON PATENT LITERATURE DOCUMENTS Examiner Cite Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. Initials\* Thome, et al., "Viral FLICE-inhibitory proteins (FLIPs) prevent apoptosis induced by death receptors", PN 61 Nature, Vol. 386, pp. 517-521, 1997. Thompson, et al., "Apoptosis in the pathogenesis and treatment of disease", Science, Vol. 267, pp. 62 1456-1462, 1995. Thornberry, et al., "Interleukin-1 β converting enzyme: a novel cysteine protease required for IL-1β 63 production and implicated in programmed cell death", Protein Science, Vol. 4, pp. 3-12, 1995. Thornberry, et al., "A combinatorial approach defines specificities of members of the caspase family and granzyme B-Functional, relationships established for key mediators of apoptosis", J. Biol. Chem., Vol. 272, pp. 17907-17911, 1997. Topalian, et al., "Tumor-specific cytolysis by lymphocytes infiltrating human melanomas", J. Immunol., Vol. 65 142, pp. 3714-3725, 1989. Trapani, et al., "Localization of granzyme B in the nucleus - A putative role in the mechanism of cytotoxic 66 lymphocyte-mediated apoptosis", J. Biol. Chem., Vol. 271, pp. 4127-4133, 1996. 67 Pietsch, et al., "Granzyme B", Methods Enzymol., Vol. 244, pp. 80-87, 1994. Wang, et al., "Identification and characterization of ICH-3, a member of the interleukin-1b converting 68 enzyme (ICE)/Ced-3 family and an upstream regulator of ICE", J. Biol. Chem., Vol. 271, pp. 20580-20587, Watts, et al., "Suppressive effect of an antibody on processing of T cell epitopes", J. Exp. Med., Vol. 178, pp. 1459-1463, 1993. 70 White, et al., "Life, death, and the pursuit of apoptosis", Genes Dev., Vol. 10, pp. 1-15, 1996. Xue, et al., "Inhibition of the Caenorhavditis elegans cell-death proteaseCED-3 by a CED-3 cleavage site in 7/ baculovirus p35 protein", Nature, Vol. 377, pp. 248-251, 1995. Yamin, et al., "Activation of the native 45-kDa precursor form of interleukin-1β-converting enzyme", J. Biol. Chem., Vol. 271, pp. 13273-13282, 1996. Young, et al., Purification and characterization of a cytolytic pore-forming protein from granules of cloned lymphocutes with natural killer activity", Cell, Vol. 44, pp. 849-859, 1986.

Attorney Docket Number

Examiner Signature	Patrick S-Nolan	Date	3/2/21	
Signature	Parsien Jovoun	Considered	3/21/0/	

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.